

REMARKS

This is a full and timely response to the outstanding non-final Office Action mailed October 30, 2007. The Applicant wishes to thank the Examiner for the thorough review of the previously submitted Amendment. In response thereto, the Applicant's arguments were fully considered and were found to be persuasive. The previous rejection has been withdrawn and the finality of the Office Action was also withdrawn.

Claims 1, and 3-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Siddiqui in view of Sparkes. The Office Action states that with respect to claims 1, 13, and 15, Siddiqui discloses an osteosynthesis and compression screw for coaptation of small bone fragments, the screw being formed by a single longitudinal body have a longitudinal axis, and comprising a proximal position formed by a screw head provided with an outside thread, the proximal portion being of diameter greater than the diameter of the remainder of the screw, and intermediate portion having no thread; and a distal portion have provided with an outside threads; as best seen in FIG. 1; the terminal zero of the distal portion is provided with preparation means for preparing a housing in the bone fragment for receiving the intermediate and distal portions of the screw.

It is noted that Siddiqui did not teach each of the screw head and the distal portion including at least one helical groove, firstly extending over the entire axial length of its threads and secondly being formed through each thread in such a manner to form tapping means, as claimed by Applicant. The Office Action continues that; however, in the screw field, Sparkes evidences the use of a screw with at least one helical groove, firstly extending over the entire axial length of its threads, and secondly being formed through each thread in such a manner to form tapping means to have exceptionally easy starting and insertion ability and to facilitate counter-sinking, and also reducing the danger of splitting the material being used.

In view of these references, the Office takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Siddiqui as taught by Sparkes to have exceptionally easy starting and insertion ability and to facilitate counter-sinking, and also reducing the danger of splitting the small bone fragments.

The Office Action continues that with respect to claims 3-12, 14, and 16-20, the above combination of references teaches all the limitations, such as, the angle being thirty degrees, the groove being constant, the variation of each groove, the increases of the grooves towards the terminal zone of the screw, the tooth extending substantially axially, the central longitudinal bore.

The above-stated rejection is respectfully traversed. Initially, the Applicant incorporates herein all the comments made concerning the Siddiqui reference from the previous amendment. The rejection is ostensibly based on the statutory provisions of 35 U.S.C. § 103, but the Applicant will hereinafter demonstrate that this reliance is misplaced. It is also apparent that the analysis set out in the Office Action is clearly an ex post facto approach and is based purely on hindsight reconstruction to arrive at the Applicant's claimed device. It is important to note the mandate set out by 35 U.S.C. § 103(a):

"a patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. "

The Applicant again appreciates the thorough review of the Applicant's prior submission by the Examiner. The Applicant reiterates all of the arguments presented earlier with regard to the combination proposed by the Office that the combination of Siddiqui, as

taught by Sparkes, renders obvious the present claims. In addition, the reference to Carchidi, et al., which has been cited but not relied upon, but considered pertinent to Applicant's disclosure, has also been carefully reviewed; however, it is believed that the Carchidi, et al. reference does not, in combination with any of the cited references, teach or make obvious the Applicant's device.

The Office's mandate is to consider "the subject matter as a whole", who is "one of ordinary skill in the art", and "the art to which said subject matter pertains". In this case, the subject matter is easy insertion of a bone screw, and the securement and compression of bone fragments. The discussion below will demonstrate that the proposed combination of Siddiqui and Sparkes, (or for that matter Carchidi, et al.) teaches away from the claimed subject matter and a designer "of ordinary skill in the art" would dismiss the proposed combination as unworkable.

A key element is missing; namely compression of the bone fragments. The question here is not that one can not combine the cited references for something, just not this subject matter. Support for this position follows.

It is acknowledged that Siddiqui does not include at least one extended helical groove, particularly in the distal portion so as to facilitate the easy starting and insertion ability and to facilitate countersinking, as taught by the Applicant. It is also acknowledged that Sparkes teaches a wood screw that is self-drilling. Sparkes incorporates a pair of spiral flutes into the body of his screw. It is the Office's position that a person skilled in the art, that is to say, a person working in the field of the surgical bone screws, and facing a problem concerning bone compression screws, would consider Sparkes to supply the necessary teaching. It is the Applicant's position that Sparkes is non-analogous art. It is analogous art for screws, but not in the art to which said subject matter pertains". The *In Re Oetiker* case, 977 F.2d 1443, 24

USPQ2d 1443 (Fed. Cir. 1992) is cited for its holding that a prior art reference must either have been in the field of Applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the Applicant was concerned in order to be relied upon as a basis for rejection of the claimed invention. The Office takes the position that: in this case, the question is not whether the combination was obvious to the Applicant but whether the combination was obvious to a person with ordinary skill in the art. Given the problem to be solved, which is incorporating a helical groove in a screw, under the correct analysis, any need or problem known in the screw field and addressed by the patents can provide a reason for combining the elements in the manner claimed. The Office continues that it is common sense that familiar items may have obvious uses beyond their primary purposes, and a person of ordinary skill in the art often will be able to fit the teachings of multiple elements together like a piece of a puzzle.

In the regard, the Office's position is misplaced. In formulating the response, the Office states that "the problem to be solved is incorporating a helical groove in the screw." Such a formulation of the problem results obviously from the use of inadmissible hindsight knowledge, because the helical shape is a part of the solution to the problem. If the problem is so formulated as to contain the solution, the solution is necessarily obvious (problem: incorporating a helical groove. "obvious" solution to this problem: incorporating a helical groove).

The Office's position continues from the standpoint that "regardless of Sparkes primary purpose, it provides an obvious example of a screw with a helical groove and the prior art was replete with patents indicating that such a helical groove was ideal for a medical device." There are such examples, (for instance, Carchidi, et al), but only for a short distance.

The reasoning behind the Office's position is flawed. Sparkes was identified in a search for screws with helical grooves, thereby using foreknowledge of the invention. There is

no reason, unless one has foreknowledge of the invention, to search for screws for helical grooves in the prior art, it being furthermore noted that the body of prior art relates to numerous different technical features, the helical shape being one feature amongst thousands of other features (International Class F16B25/00, directed to auto tapping screws, includes more than 3,000 published documents at the priority date of the instant application). The Applicant is held to know the prior art. Confronted with the problem here, the answer is not found in the combination of Siddiqui and Sparkes.

A review of the Sparkes device is in order. Sparkes teaches a wood screw that is self-tapping for easy starting and insertion ability. The screw has a first spiral flute passing essentially the full length of the screw. A second spiral flute begins at the point of the screw but continues only a short distance therefrom. This allows the screw to be inserted into wood without the necessity for drilling a pilot hole. Wood screws by their nature are meant to hold two separate wooden objects together. The purpose of the flutes in the wood screw of Sparkes is set out in column 2, lines 24 through 30 wherein it is stated, "this angle should be about 30 degrees to properly convey the wood cuttings from the pilot hole drilled by the screw, itself. The angle should not be so great as to tend to drive the wood screw into the wood, but a certain amount of spiral is appropriate to assist in conveying the wood cuttings upwardly." Further in the same column, namely column 2, lines 57 through 59, it is stated that "the wood cuttings in the long spiral tend to be compressed and create an exceptionally strong fastening quality of the screw in the wood." In other words, the wood cuttings which are dislodged and travel upwardly through the flutes, actually help to secure the screw in place. It is submitted that one of ordinary skill in the art of bone screws, would dismiss Sparkes as providing a construction that is difficult to remove, unlike the device of the Applicant. Further, attention is directed to the next statement of Sparkes in column 2, lines 59-62 where it is stated that "the

spiral flute through the threads act as a tap, cutting clean threads in the wood rather than compressing and splitting or weakening the material."

The problem to be solved by the Applicant is the problem formulated in the application, namely providing a compression screw for small bones that is very "aggressive" while also exhibiting the required strength. The Applicant's screw must also fasten and compress the bone fragments. The prior art gave no hint of providing a helical shaped groove in a prescribed length, as claimed herein, for solving this problem, and the above discussion refutes the position taken by the Office that a designer would follow the teaching of Sparkes. It is believed plainly obvious that a designer presented with Siddiqui and knowing of Sparkes, would conclude that Sparkes teaches away from the solution achieved by the Applicant.

The Office opines that where there is a design need or market pressure to solve a problem and there are a finite number of identified procedural solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. The Office continues with the statement that the proper question was whether a bone screw device designer of ordinary skill in the art, facing a wide range of needs created by the developments in the screw fields, would have seen an obvious benefit to upgrading Siddiqui with a helical groove. (Emphasis added). But Sparkes teaches a screw with a helical groove to have easy starting ability and to facilitate counter sinking and also reducing the danger of splitting the material being used to assure reliable operation while not compressing the joined members. This does not lead to the conclusion that the designer accordingly, would follow the teaching of Sparkes.

The Office's position is believed to be now effectively refuted by the above discussion. In addition, with respect to Sparkes and Carchidi, et al., which is cited by the Office to allege that "a helical groove was ideal for a medical device," the present disclosure teaches a screw

with a helical groove extending over the entire or substantially the entire axial length of its thread. This feature is important because it confers aggressivity to the screw, without harming the ability of the screw to be secured in the bone. In addition, the aggressive nature of the Applicant's device is not taught by Carchidi et al. since the Carchidi et al. screw has no thread at its distal tip but only a twist drill tip.

In contrast, the existence of grooves in the distal thread of Carchidi, et al., and Siddiqui, teach the implementation of distal grooves that are very short, contrary to the Applicant's device. There are other prior art references in which it is taught that there is a technical prejudice against the use of long distal grooves. One explanation to this consistent prior art teaching in the medical screw field, that grooves must be of a short length, is that a long distal groove would generate an accumulation of bone cutting at the interface between the two bone fragments, that is to say in the zone of the fracture (this is clearly shown in Sparkes, in Fig. 2 and column 2, lines 9-10). However, the presence of bone cuttings in the fracture zone must be proscribed because the cut material is likely to prevent the bringing together and the perfect maintaining of the bone fragments. Thus, one skilled in the art would dismiss modifying the short grooves of Siddiqui or Carchidi et al., with the long grooves of Sparkes. This is clearly stated in page 1, lines 26-29 of prior art document FR2787313 (copy enclosed), published in 2000: <<L'emploi de vis induit également un risqué d'arrachement et de refoulement de matière osseuse au niveau de la zone de fracture, cette matière venant ensuite s'opposer au rapprochement et au parfait maintien des fragments en contact mutuel>> which can be translated as follows: "using screws generates a risk of wrenching and of driving back bony matter at the fracture zone, said bony matter preventing the bringing together and the perfect maintaining of the bone fragments". The Applicant found this potential drawback (bone cuttings in the fracture zone) to be acceptable given the other benefits of the device, and thus

overcame the technical prejudice and conventional teaching that say it is important to avoid such accumulation of bone cutting at the interface of the fracture. Lastly, even if the skilled person follows the teaching of Sparkes, they would only give a helical shape to the straight grooves of Siddiqui, and thus would not arrive at the invention, since the now helical grooves would remain short.

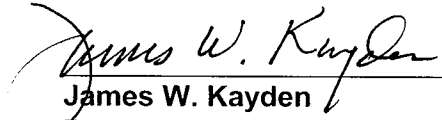
Given such requirements, it is submitted that the Office has taken the wrong view of the present device. The Office Action states that “the proper question was whether a bone screw device designer of ordinary skill in the art, facing a wide range of needs created by the developments in the screw fields, would have seen an obvious benefit to upgrading Siddiqui with a helical groove.” The bone screw designer is not concerned with the wide range of needs created by developments in the screw fields, but instead is concerned with the compression of bone fragments, the minimization of the dislodging or cutting of bone that is being penetrated, the securement of the bone fragments together so that healing can be effected, and finally, in some cases, the ease with which the screw can be withdrawn. None of these features can be achieved with the combination of Siddiqui and Sparkes, or any of the other cited prior art of record. The Applicant, presented with the proposed combination, reviews the references, dismisses them as not teaching a workable combination, and designs a novel approach, exactly as the statutes contemplate.

The independent claims all teach features not found in the cited prior art. The dependant claims also teach additional features not taught by the cited prior art. It is therefore submitted, that all of the claims in the present application are indeed in condition for allowance. The combination of references, given a careful and detailed review, would not suggest to one of ordinary skill in the art that the proposed combination would be in any sense desirable to solve the problem addressed by the Applicant.

CONCLUSION

It is for these and other reasons enunciated earlier that it is believed that all of the claims remaining in the Application are in condition for allowance. Early and favorable action in this regard is hereby respectfully requested. Should there be any minor informalities remaining, or if, in the opinion of the Examiner, a telephone conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,


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